



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/285,559 04/02/99 HECHEL

D 3216/75036

QM12/1219

EXAMINER

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ART UNIT

PAPER NUMBER

3737

DATE MAILED: 12/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/285,559

Applicant(s)

HECHEL ET AL.

Examiner

Runa S Qaderi

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 4,5,14, and 15 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 4, 5, 14, and 15 are objected to because of the following informalities:

Consistency is required in describing the visual indicator in claims 4, 5, 14, and 15.

Claim 4 line 3 describes the visual indicator as "thermochromic" and later in the same claim, line 6 as "thermalchromic". The two terms are interchangeably used in claims 4, 4, 14, and 15.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and 4 are rejected as being incomplete in that claiming apparatus for applying ultrasound in the preamble but no ultrasound system positively claimed.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1-7 and 12-17 are rejected under 35 U.S.C. 101 for claiming the human body. The office holds that unless biological matter is part of the invention. It can not be claimed.

Claim 1, line 3 applicant recites "means disposed on the portion"

Claim 4, line 3 applicant recites "a thermochromic strip disposed on the portion"

Claim 12, line 3 applicant recites "means disposed on the portion"

Use of "adapted to be" or some similar way which does not positively set forth the human body or portions thereof as part of the claimed subject matter would be one way to solve this problem.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chervitz, patent number 4,509,533.

Chervitz discloses an adhesive visual indicator that changes color in response to temperature and is adapted to be disposed on the body portion, column 2, lines 4-17.

Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Watmough et al., patent number 4,889,122.

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Watmough et. al disclose a method of applying ultrasound treatment wherein a temperature sensing visual indicator is in contact with treated tissue, column 3 lines 21-23 and 30-33. In addition Watmough et. al disclose that frequency of the ultrasound is altered to alter depth and temperature distribution, column 3 lines 37-44.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 6, 7, and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watmough et. al in view of Chervitz.

In regard to claims 2, 3, 6, 7, and 12-17 Watmough et. al differs from the claimed invention in that a securing mechanism via an adhesive backing is not addressed. Other features of the strip that are not addressed in Watmough et. al include strip further comprising of a plastic sandwich, colored background, and alpha-numeric characters. Chervitz discloses a visual indicator with an adhesive backing, and comprising of a plastic sandwich, colored backing, a numeric characters. See abstract, column 1 lines 14-17, and column 2 lines 4-9. It would have been obvious at the time

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the invention was made to a person of ordinary skill in the art to substitute alpha-numeric characters for numeric characters.

***Claim Rejections - 35 USC § 102/103***

6. Claim 11 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Watmough et. al, patent number 4,889,122.

In regard to claim 11 Watmough et. al disclose a computer simulation for determining skin temperature, ultrasound absorption, thermal conduction, and different power settings of the transducer on the temperature distribution inside the tissue during local hyperthermia. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to determine an average depth of penetration of the ultrasound for the selected frequency, column 5 lines 13-16. Average is construed to mean typical or normal in this claim. Warmough et. al teach a method that is applicable for predicting effected tissue characteristics due to ultrasound treatment.

***Prior Art of Record***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Name, patent number

Navato, 4,030,482

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McNaughtan, 4,070,912

Inoue et. al, 4,154,106

Mung-Kuen Luk, 4,198,861

Chervitz, 4,232,684

Luk, 4,302,971

Chervitz, 4,333,477

Nelson, 4,437,471

Klopotek, 5,230,334

Cline, 5,291,890

Bock, 5,618,275

Marzorati, 5,776,076

Smith, 5,947,988

Silberg, 6,039,048

Slayton et. al, 6,050,943

Gouge et.al, 6,067,371

Cribbs et. al, 6,071,239

Klopotek, 6,113,559

Bechtold et. al, 6,128,523

Brounstein, 6,138,968

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**Conclusion**

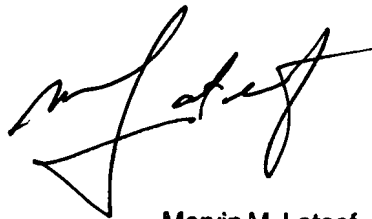
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

RQ  
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December 1, 2000



Marvin M. Lateef  
Supervisory Patent Examiner  
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